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## PATENT COOPERATION TREATY

PCT

## NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

United States Patent and Trademark  
Office  
(Box PCT)  
Crystal Plaza 2  
Washington, DC 20231  
ÉTATS-UNIS D'AMÉRIQUE

in its capacity as elected Office

<b>Date of mailing</b> (day/month/year) 09 February 1999 (09.02.99)	
<b>International application No.</b> PCT/EP97/03099	<b>Applicant's or agent's file reference</b> 97/08217 WO
<b>International filing date</b> (day/month/year) 13 June 1997 (13.06.97)	<b>Priority date</b> (day/month/year)
<b>Applicant</b> SABEL, Bernhard, A. et al	

1. The designated Office is hereby notified of its election made:

☒ in the demand filed with the International Preliminary Examining Authority on:

13 January 1999 (13.01.99)

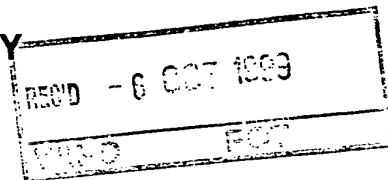
☐ in a notice effecting later election filed with the International Bureau on:2. The election ☒ was☐ was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

<b>The International Bureau of WIPO</b> 34, chemin des Colombettes 1211 Geneva 20, Switzerland	<b>Authorized officer</b> Eugénia Santos
Facsimile No.: (41-22) 740.14.35	Telephone No.: (41-22) 338.83.38

## PATENT COOPERATION TREATY

## PCT



## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

18

Applicant's or agent's file reference 97/08217 WO		<b>FOR FURTHER ACTION</b> See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)	
International application No. PCT/EP97/03099	International filing date (day/month/year) 13/06/1997	Priority date (day/month/year) [13/06/1997] none	
International Patent Classification (IPC) or national classification and IPC A61K9/51			
Applicant MEDINOVA MEDICAL CONSULTING GMBH et al.			

1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.


2. This REPORT consists of a total of 5 sheets, including this cover sheet.

- ☐ This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).

These annexes consist of a total of sheets.

3. This report contains indications relating to the following items:

- I ☒ Basis of the report
- II ☐ Priority
- III ☒ Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- IV ☐ Lack of unity of invention
- V ☒ Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- VI ☐ Certain documents cited
- VII ☐ Certain defects in the international application
- VIII ☐ Certain observations on the international application

Date of submission of the demand 13/01/1999	Date of completion of this report 04.10.99
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Toulacis. C 

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/EP97/03099

**I. Basis of the report**

1. This report has been drawn on the basis of (*substitute sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to the report since they do not contain amendments.*):

**Description, pages:**

1-26 as originally filed

**Claims, No.:**

1-40 as originally filed

**Drawings, sheets:**

1/5-5/5 as originally filed

2. The amendments have resulted in the cancellation of:

- ☐ the description, pages:  
☐ the claims, Nos.:  
☐ the drawings, sheets:

3. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

4. Additional observations, if necessary:

**III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.  
☒ claims Nos. 31-40.

because:

**INTERNATIONAL PRELIMINARY  
EXAMINATION REPORT**

International application No. PCT/EP97/03099

- ☒ the said international application, or the said claims Nos. 31-40 relate to the following subject matter which does not require an international preliminary examination (*specify*):

**see separate sheet**

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):

- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.

- ☐ no international search report has been established for the said claims Nos. .

**V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

**1. Statement**

Novelty (N)	Yes:	Claims	
	No:	Claims	1-40
Inventive step (IS)	Yes:	Claims	
	No:	Claims	1-40
Industrial applicability (IA)	Yes:	Claims	1-30
	No:	Claims	

**2. Citations and explanations**

**see separate sheet**

**III**

Claims 31-40 relate to a method for medical treatment of the human or animal body.

**V**

- (N) A drug targeting system for administration to a mammal comprising nanoparticles made of a polymeric material, said nanoparticles comprising said polymeric material, one or more physiologically effective substance(s) to be delivered to said mammal and one or more stabilizer(s) for said nanoparticles allowing targeting of said physiologically effective substance(s) to a specific site within or on a mammalian body, and a physiologically acceptable carrier and/or diluent allowing the transport of said nanoparticles to the target within said mammal after administration, as defined in claims 1 to 14 of the present application, is already disclosed in documents WO95/22963 (D1), WO94/15590 (D2), EP-A-0 330 180 (D3), EP-A-0 486 959 (D4) and FR-A-2 612 400 (D5). The same applies to the method for preparing said drug targeting systems (claims 15-30) and to the use of said drug targeting system for the preparation of a medicament (claims 31-37) and to the method as defined in claims 38 to 40 of the present application.

The relevant passages are: D1; page 7, lines 8-13; page 9 -page 13; examples 1, 2; claims 1-30 -- D2; page 1, lines 5-8; page 2, line 3-4, 25-30; page 4, lines 13-15; page 5, lines 7-10; page 6, line 22 - page 7, line 2; page 7, lines 20-23; page 9, line 28 - page 10, line 14; example 8 -- D3; abstract; page 4, lines 8-17; page 5, lines 2-25; example 1 -- D4; abstract; page 3, line 43; page 4, lines 6-7; examples; claims 1-6 -- D5; abstract; page 3, line 39 - page 4, line 6; page 8, line 37 - page 9, line 27; page 9, lines 36-38; claims 2,9,14 and 15.

The stabilizers used according to the present application are defined in claims 9 to 13 and in the description page 18, last paragraph to page 19, third paragraph.

Such substances are disclosed in the documents D1 to D5 mentioned above.

The expression "... and one or more stabilizer(s) for said nanoparticles allowing targeting of said physiologically effective substance(s) to a specific site within or on a mammalian body;" in claim 1, characterises the invention by indication of the result to be achieved (cf. description, page 4, paragraph 3), and does not imply any technical feature which would distinguish the claimed subject-matter from that known from the prior art (Guidelines C-IV 7.6 PCT).

- (IS) The question - Is there inventive step - only arises if there is novelty.  
Moreover, it appears that the problem which faced the skilled man at the priority date of the present Application (description page 4, last paragraph) has already been described and solved in document D1 (D1; page 5, paragraph 3 to page 6, paragraph 4).
- (IA) The industrial applicability is beyond any doubt.

Industrial applicability of claims 31-40

The wording of claims 31-37 "Use of the drug targeting system in the preparation of a medicament allowing one or more physiologically effective substance(s) to be targeted to a specific site within or on a mammalian body" is not clearly directed to the use of said system for the preparation of a medicament. The claimed use in the preparation of a medicament is still directed to the medicament as such. However, the use of a medicament allowing one or more physiologically effective substance(s) to be targeted to a specific site within or on a mammalian body, relates to a method for medical treatment of the human or animal body. Claims 38-40 directly relate to a method for medical treatment of the human or animal body.

For the assessment of the present claims 31-40 on the question whether they are industrially applicable no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims directed to the use of a compound in medical treatment, but may allow, however, claims directed to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

## PCT

## INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference <b>97/08217 WO</b>	<b>FOR FURTHER ACTION</b> see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. <b>PCT/EP 97/ 03099</b>	International filing date (day/month/year) <b>13/06/1997</b>	(Earliest) Priority Date (day/month/year)
Applicant <b>MEDINOVA MEDICAL CONSULTING GMBH et al.</b>		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 3 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. ☐ Certain claims were found unsearchable (see Box I).
2. ☐ Unity of invention is lacking (see Box II).
3. ☐ The international application contains disclosure of a **nucleotide and/or amino acid sequence listing** and the international search was carried out on the basis of the sequence listing
- ☐ filed with the international application.
  - ☐ furnished by the applicant separately from the international application,
    - ☐ but not accompanied by a statement to the effect that it did not include matter going beyond the disclosure in the international application as filed.
  - ☐ Transcribed by this Authority

4. With regard to the **title**, ☐ the text is approved as submitted by the applicant  
☒ the text has been established by this Authority to read as follows:

**DRUG TARGETING SYSTEM, METHOD OF ITS PREPARATION AND ITS USE**

5. With regard to the **abstract**,
- ☒ the text is approved as submitted by the applicant
  - ☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this International Search Report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is:

Figure No. \_\_\_\_\_ ☐ as suggested by the applicant.  
☐ because the applicant failed to suggest a figure.  
☐ because this figure better characterizes the invention.

☒ None of the figures.



# INTERNATIONAL SEARCH REPORT

National Application No

PCT/EP 97/03099

**A. CLASSIFICATION OF SUBJECT MATTER**  
IPC 6 A61K9/51

According to International Patent Classification (IPC) or to both national classification and IPC

**B. FIELDS SEARCHED**

Minimum documentation searched (classification system followed by classification symbols)  
IPC 6 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

**C. DOCUMENTS CONSIDERED TO BE RELEVANT**

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>WO 95 22963 A (MEDINOVA MED CONSULTING GMBH) 31 August 1995 cited in the application see abstract see page 7, line 8-13 see page 9 - page 13 see example 2 see claims</p> <p style="text-align: center;">--- -/--</p>	1-40

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

° Special categories of cited documents :

"A" document defining the general state of the art which is not considered to be of particular relevance  
"E" earlier document but published on or after the international filing date  
"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)  
"O" document referring to an oral disclosure, use, exhibition or other means  
"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention  
"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone  
"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.  
"&" document member of the same patent family

Date of the actual completion of the international search

2 February 1998

Date of mailing of the international search report

10/02/1998

Name and mailing address of the ISA

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NL - 2280 HV Rijswijk  
Tel. (+31-70) 340-2040, Tx. 31 651 epo nl,  
Fax: (+31-70) 340-3016

Authorized officer

La Gaetana, R

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 97/03099

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>WO 94 15590 A (ABACOL LTD ;DYATLOV VALERY A (RU); KATZ GEORGY ARKADIEVICH (RU)) 21 July 1994  see abstract  see page 1, line 5-8  see page 2, line 3-4  see page 2, line 25-30  see page 4, line 13-15  see page 5, line 7-10  see page 6, line 22 - page 7, line 2  see page 7, line 20-23  see page 9, line 28 - page 10, line 14  see example 8</p> <p style="text-align: center;">---</p>	<p>1-12, 15, 18, 20-25</p>
X	<p>EP 0 330 180 A (BIOMATERIALS UNIVERSE INC) 30 August 1989  see abstract  see page 4, line 8-17  see page 5, line 2-15  see example 1</p> <p style="text-align: center;">---</p>	<p>1-6, 8-12, 15, 18-40</p>
X	<p>EP 0 486 959 A (VECTORPHARMA INT) 27 May 1992  see abstract  see page 3, line 43  see page 4, line 6-7  see examples  see claims 1-6</p> <p style="text-align: center;">---</p>	<p>1-6, 8-12, 15, 18-40</p>
X	<p>FR 2 612 400 A (CENTRE NAT RECH SCIENT ;UNIV ANGERS (FR)) 23 September 1988  see abstract  see page 3, line 39 - page 4, line 6  see page 8, line 37 - page 9, line 27  see page 9, line 36-38; claims 2, 9, 14, 15</p> <p style="text-align: center;">-----</p>	<p>1-5, 8-12, 15, 18-25, 28-30</p>

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP 97/03099

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
WO 9522963 A	31-08-95	AU 1947395 A CA 2184242 A EP 0740548 A HU 75469 A JP 9506109 T	11-09-95 31-08-95 06-11-96 28-05-97 17-06-97
WO 9415590 A	21-07-94	AU 5714194 A AU 5714294 A CA 2153342 A EP 0682513 A EP 0682651 A WO 9415907 A JP 8505383 T PL 310072 A PL 310073 A	15-08-94 15-08-94 21-07-94 22-11-95 22-11-95 21-07-94 11-06-96 27-11-95 27-11-95
EP 0330180 A	30-08-89	JP 1216918 A JP 2670680 B US 5100669 A	30-08-89 29-10-97 31-03-92
EP 0486959 A	27-05-92	IT 1243390 B AT 141788 T DE 69121675 D DE 69121675 T ES 2094781 T JP 4283510 A US 5536508 A US 5700486 A	10-06-94 15-09-96 02-10-96 06-03-97 01-02-97 08-10-92 16-07-96 23-12-97
FR 2612400 A	23-09-88	NONE	



## INTERNATIONAL APPLICATION PUBLISHED UNDER THE PATENT COOPERATION TREATY (PCT)

<b>(51) International Patent Classification <sup>6</sup> :</b>  <b>A61K 9/51</b>	<b>A1</b>	<b>(11) International Publication Number:</b> <b>WO 98/56361</b>  <b>(43) International Publication Date:</b> 17 December 1998 (17.12.98)
<b>(21) International Application Number:</b> PCT/EP97/03099  <b>(22) International Filing Date:</b> 13 June 1997 (13.06.97)  <b>(71) Applicant (for all designated States except US):</b> MEDINOVA MEDICAL CONSULTING GMBH [DE/DE]; Hansapark 2, D-39116 Magdeburg (DE).  <b>(72) Inventors; and</b> <b>(75) Inventors/Applicants (for US only):</b> SABEL, Bernhard, A. [DE/DE]; Kronprinzessinnenweg 13, D-14109 Berlin (DE). SCHROEDER, Ulrike [DE/DE]; Am Sülzhang 7, D-39171 Dodendorf (DE).  <b>(74) Agents:</b> KOEPE, Gerd, L. et al.; Blumbach, Kramer & Partner, Radeckestrasse 43, D-81245 München (DE).		<b>(81) Designated States:</b> AL, AM, AT, AU, AZ, BA, BB, BG, BR, BY, CA, CH, CN, CU, CZ, DE, DK, EE, ES, FI, GB, GE, GH, HU, IL, IS, JP, KE, KG, KP, KR, KZ, LC, LK, LR, LS, LT, LU, LV, MD, MG, MK, MN, MW, MX, NO, NZ, PL, PT, RO, RU, SD, SE, SG, SI, SK, TJ, TM, TR, TT, UA, UG, US, UZ, VN, YU, ARIPO patent (GH, KE, LS, MW, SD, SZ, UG, ZW), Eurasian patent (AM, AZ, BY, KG, KZ, MD, RU, TJ, TM), European patent (AT, BE, CH, DE, DK, ES, FI, FR, GB, GR, IE, IT, LU, MC, NL, PT, SE), OAPI patent (BF, BJ, CF, CG, CI, CM, GA, GN, ML, MR, NE, SN, TD, TG).  <b>Published</b> <i>With international search report.</i>
<b>(54) Title:</b> DRUG TARGETING SYSTEM, METHOD OF ITS PREPARATION AND ITS USE		
<b>(57) Abstract</b>  <p>A composition and method of fabrication are presented with which nanoparticles may be used as a tool to deliver drugs to a specific target within or on a mammalian body. Specifically, by using stabilizers other than Dextran 70.000 during the polymerization process, according to the present invention, surfactants, which were deemed necessary coating material in the prior art, are no longer required. This is a significant simplification of the fabrication procedure. Many substances are useful as stabilizers, but the preferred stabilizers comprise Dextran 12.000 or polysorbate 85. In the present invention a drug is either incorporated into or adsorbed onto the stabilized nanoparticles. This drug/nanoparticle complex is then administered to the organism on any route such as by oral application, injection or inhalation, whereupon the drug exerts its effect at the desired site of pharmacological action. In a novel medical treatment process, the drug/nanoparticle complex may be administered preferably either by intravenous injection or by oral application. The resulting drug action, which does not occur or which occurs only to an insufficient extent when the drug is administered alone, shows that when linked to said nanoparticles drugs can reach a specific target within or on the mammalian body. The usefulness of the present invention as a universal approach to deliver any drug or diagnostic agent to a specific target within or on the mammalian body was demonstrated by experiments showing an unexpected transfer of the drug across the blood brain barrier.</p>		

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EE	Estonia	LR	Liberia	SG	Singapore		

# INTERNATIONAL SEARCH REPORT

Int. l. Application No

PCT/EP 97/03099

## A. CLASSIFICATION OF SUBJECT MATTER

IPC 6 A61K9/51

According to International Patent Classification(IPC) or to both national classification and IPC

## B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 6 A61K

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

## C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>WO 95 22963 A (MEDINOVA MED CONSULTING GMBH) 31 August 1995  cited in the application  see abstract  see page 7, line 8-13  see page 9 - page 13  see example 2  see claims</p> <p style="text-align: center;">--- -/--</p>	1-40

☒ Further documents are listed in the continuation of box C.

☒ Patent family members are listed in annex.

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"P" document published prior to the international filing date but later than the priority date claimed

"T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention

"X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone

"Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.

"&" document member of the same patent family

Date of the actual completion of the international search

2 February 1998

Date of mailing of the international search report

10/02/1998

Name and mailing address of the ISA

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Fax: (+31-70) 340-3016

Authorized officer

La Gaetana, R

# INTERNATIONAL SEARCH REPORT

International Application No

PCT/EP 97/03099

## C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
X	<p>WO 94 15590 A (ABACOL LTD ;DYATLOV VALERY A (RU); KATZ GEORGY ARKADIEVICH (RU)) 21 July 1994  see abstract  see page 1, line 5-8  see page 2, line 3-4  see page 2, line 25-30  see page 4, line 13-15  see page 5, line 7-10  see page 6, line 22 - page 7, line 2  see page 7, line 20-23  see page 9, line 28 - page 10, line 14  see example 8</p> <p style="text-align: center;">---</p>	<p>1-12, 15,  18, 20-25</p>
X	<p>EP 0 330 180 A (BIOMATERIALS UNIVERSE INC) 30 August 1989  see abstract  see page 4, line 8-17  see page 5, line 2-15  see example 1</p> <p style="text-align: center;">---</p>	<p>1-6,  8-12, 15,  18-40</p>
X	<p>EP 0 486 959 A (VECTORPHARMA INT) 27 May 1992  see abstract  see page 3, line 43  see page 4, line 6-7  see examples  see claims 1-6</p> <p style="text-align: center;">---</p>	<p>1-6,  8-12, 15,  18-40</p>
X	<p>FR 2 612 400 A (CENTRE NAT RECH SCIENT ;UNIV ANGERS (FR)) 23 September 1988  see abstract  see page 3, line 39 - page 4, line 6  see page 8, line 37 - page 9, line 27  see page 9, line 36-38; claims 2, 9, 14, 15</p> <p style="text-align: center;">-----</p>	<p>1-5,  8-12, 15,  18-25,  28-30</p>

# INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/EP 97/03099

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
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